

## REMARKS

In the Office Action, claims 1-20 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Lalonde et al. (US 6,283,959) in view of Benson (US 4,082,096).

In this Response to Office Action, independent claims 1, 8 and 15 have been amended to now recite a device (claims 1 and 8) or method (claim 15) for cryoablating tissue that includes a flow restricting device or capillary tube. Support for these amendments is found in the specification beginning on page 4, lines 4-17, page 7, lines 10-20 and in Figs. 2 and 3. In addition to these amendments, claims 6 and 20 have been amended to accommodate amendments to independent claims 1 and 15, respectively, and a typographical error has been corrected in claim 13.

Amendments to the claims have been presented herein to improve the readability of the claims and to point out the features which distinguish the present invention over the cited art. Also, these amendments have been made to more clearly define the structure and cooperation of structure for the present invention. Claims 1-20 remain pending.

### Rejections under 35 U.S.C. § 103(a)

In the Office Action, claims 1-20 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Lalonde et al. (US 6,283,959) in view of Benson (US 4,082,096). Specifically, the Examiner has indicated that Lalonde et al. disclose a device for cryoablating exposed tissue comprising a tube-shaped shaft, a flexible

enclosure and a means for cooling the enclosure. The Examiner has further indicated that Benson discloses a shapeable element that helps to maintain the desired configuration of a contact tip and provides a means for pressing the probe tip into engagement with tissues.

In this Response to Office Action, all independent claims (i.e. claims 1, 8 and 15) have been amended and now recite a device (claims 1 and 8) or method (claim 15) for cryoablating tissue that includes a flexible enclosure that forms a cryochamber, a shapeable member that is positioned in the cryochamber, and a flow restricting device (claims 8 and 15) or capillary tube (claim 1) for restricting a flow of a cryo-fluid into the cryochamber. The specification indicates that restricting the flow of cryo-fluid in this manner provides more efficient cooling as compared to a non-restricted flow, and in some cases, can be used to ensure that the cryo-fluid transitions from a liquid state to a gaseous state as it expands into the cryochamber (see, for example, page 4, lines 4-15).

No such structure or cooperation of structure is taught or suggested by either of the cited references (i.e. Lalonde et al. or Benson), taken alone or in combination. Specifically, neither reference teaches or suggests the use of a flow restricting device as now claimed by all independent claims (i.e. claims 1, 8 and 15) for the present application. Considering the Benson reference first, no such flow restriction device is disclosed. Instead, for the Benson device, a vented coolant dispenser is suggested. Operationally, when the dispenser vent is closed, coolant evaporation increases the pressure in the dispenser and causes coolant to flow out of the dispenser through a supply tube. From the supply tube, coolant is released directly into a mass of

deformable material. Importantly, no restricting device or capillary tube is disclosed by Benson to restrict coolant flow in the supply tube.

The teaching that is lacking in Benson is not provided by the Lalonde et al. reference. Specifically, the Lalonde et al. reference does not disclose the use of a flow restricting device. Instead, the Lalonde et al. reference is directed toward an endovascular, flexible balloon catheter in which the balloon is cooled, and in some cases inflated with, a cryogenic fluid. Importantly, the balloon catheter disclosed by Lalonde et al. does not employ a flow restricting device. Also, the Lalonde et al. reference effectively teaches away from the use of phase change and high pressure coolants. Specifically, the Lalonde et al. reference states that the expansion of high pressure or phase change coolants can create turbulence which can cause unwanted variations in coolant flow and cooling power as the balloon is inflated (see Lalonde et al. beginning at col. 1, line 56 and continuing to col. 2 line 11).

In addition to the deficiencies in the cited art that are described above, Attorney for Applicant respectfully contends that there is no motivation to combine the teachings of Benson with the teachings of Lalonde et al. as suggested by the Examiner. As indicated above and relevant to the present discussion, the Lalonde et al. reference is directed toward an endovascular, flexible balloon catheter in which the balloon is cooled, and in some cases inflated with, a cryogenic fluid. Importantly, the Examiner has correctly pointed out that the Lalonde et al. reference does not employ the use of a shapeable element within a cryochamber. Thus, unlike the present invention which uses a shapeable element to establish the contact area between the device and exposed tissue, for the Lalonde et al. device, it is the shape of the flexible balloon that

establishes and controls the size and shape of the cooling surface / tissue interface. As a consequence, the use of a shapeable element in the endovascular, balloon catheter disclosed by Lalonde et al. would be functionally redundant, and most likely inoperative. With the above in mind, Attorney for Applicant respectfully contends that there is no motivation for the skilled artisan to modify the Lalonde et al. device with a shapeable member as suggested by the Examiner.


In view of the arguments presented above for distinguishing amended independent claims 1, 8 and 15 over the cited references (i.e. Lalonde et al. and Benson), Attorney for Applicant respectfully contends that these claims are now allowable. Accordingly, since rejected claims 2-7, 9-14 and 16-20 respectively depend either directly or indirectly from independent claim 1, 8 or 15, these claims are also allowable. For the reasons set forth above, Applicant believes the basis for rejecting claims 1-20 under 35 U.S.C. § 103(a) has been overcome and the rejections should be withdrawn.

The references cited by the Examiner, but not relied on for the rejection of claims, have been noted.

In conclusion, Applicant respectfully asserts that claims 1-20 are patentable for the reasons set forth above, and that the application is now in a condition for allowance. Accordingly, an early notice of allowance is respectfully requested. The Examiner is requested to call the undersigned at 619-688-1300 for any reason that would advance the instant application to issue.

- Dated this 20<sup>th</sup> day of August, 2004.

Respectfully submitted,



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